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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/737,290	12/15/2003	Katherine S. Bowdish	ALEX-P04-054	6650

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EXAMINER	
TUNGATURTHI, PARITHOSH K	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 11/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/737,290	BOWDISH ET AL.	
	Examiner	Art Unit	
	Parithosh K. Tungaturthi	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9 and 14 in part, drawn to an immunoglobulin molecule or fragment thereof comprising a region where amino resides corresponding to at least a portion of a complementary determining regions (CDR) is replaced with a peptide consisting of hBNP and hBNP mimetics, classified in class 530 and subclass 387.1+.

II. Claims 1-9 and 14 in part, drawn to an immunoglobulin molecule or fragment thereof comprising a region where amino resides corresponding to at least a portion of a complementary determining regions (CDR) is replaced with a peptide consisting of GLP-1 and GLP-1 mimetics, classified in class 530 and subclass 387.1+.

III. Claims 1-9 and 14 in part, drawn to an immunoglobulin molecule or fragment thereof comprising a region where amino resides corresponding to at least a portion of a complementary determining regions (CDR) is replaced with a peptide consisting of GLP-2 and GLP-2 mimetics, classified in class 530 and subclass 387.1+.

IV. Claims 1-9 and 14 in part, drawn to an immunoglobulin molecule or fragment thereof comprising a region where amino resides corresponding to at least a portion of a complementary determining regions (CDR) is

replaced with a peptide consisting of exendin and exendin mimetics, classified in class 530 and subclass 387.1+.

V. Claims 1-9 and 14 in part, drawn to an immunoglobulin molecule or fragment thereof comprising a region where amino resides corresponding to at least a portion of a complementary determining regions (CDR) is replaced with a peptide consisting of glucagon and glucagon mimetics, classified in class 530 and subclass 387.1+.

VI. Claims 1-9 and 14 in part, drawn to an immunoglobulin molecule or fragment thereof comprising a region where amino resides corresponding to at least a portion of a complementary determining regions (CDR) is replaced with a peptide consisting of PACAP-38, classified in class 530 and subclass 387.1+.

VII. Claims 10-13 in part, drawn to a nucleic acid encoding an immunogenic molecule or fragment thereof and a method of producing an immunoglobulin molecule, wherein the immunoglobulin molecule or fragment thereof comprising a region where amino resides corresponding to at least a portion of a complementary determining regions (CDR) is replaced with a peptide consisting of hBNP and hBNP mimetics, classified in class 536 and subclass 23.1.

VIII. Claims 10-13 in part, drawn to a nucleic acid encoding an immunogenic molecule or fragment thereof and a method of producing an immunoglobulin molecule, wherein the immunoglobulin molecule or

fragment thereof comprising a region where amino resides corresponding to at least a portion of a complementary determining regions (CDR) is replaced with a peptide consisting of GLP-1 and GLP-1 mimetics, classified in class 536 and subclass 23.1.

IX. Claims 10-13 in part, drawn to a nucleic acid encoding an immunogenic molecule or fragment thereof and a method of producing an immunoglobulin molecule, wherein the immunoglobulin molecule or fragment thereof comprising a region where amino resides corresponding to at least a portion of a complementary determining regions (CDR) is replaced with a peptide consisting of GLP-2 and GLP-2 mimetics, classified in class 536 and subclass 23.1.

X. Claims 10-13 in part, drawn to a nucleic acid encoding an immunogenic molecule or fragment thereof and a method of producing an immunoglobulin molecule, wherein the immunoglobulin molecule or fragment thereof comprising a region where amino resides corresponding to at least a portion of a complementary determining regions (CDR) is replaced with a peptide consisting of exendin and exendin mimetics, classified in class 536 and subclass 23.1.

XI. Claims 10-13 in part, drawn to a nucleic acid encoding an immunogenic molecule or fragment thereof and a method of producing an immunoglobulin molecule, wherein the immunoglobulin molecule or fragment thereof comprising a region where amino resides corresponding

to at least a portion of a complementary determining regions (CDR) is replaced with a peptide consisting of glucagon and glucagon mimetics, classified in class 536 and subclass 23.1.

XII. Claims 10-13 in part, drawn to a nucleic acid encoding an immunogenic molecule or fragment thereof and a method of producing an immunoglobulin molecule, wherein the immunoglobulin molecule or fragment thereof comprising a region where amino resides corresponding to at least a portion of a complementary determining regions (CDR) is replaced with a peptide consisting of PACAP-38, classified in class 536 and subclass 23.1.

XIII. Claim 15, drawn to a method of treating congestive heart failure comprising administering a subject an immunogenic molecule or fragment thereof and a method of producing an immunoglobulin molecule, wherein the immunoglobulin molecule or fragment thereof comprising a region where amino resides corresponding to at least a portion of a complementary determining regions (CDR) is replaced with a peptide consisting of hBNP and hBNP mimetics, classified in class 514, subclass 2, for example.

XIV. Claim 16 in part, drawn to a method of treating diabetes comprising administering to a subject an immunoglobulin molecule or fragment thereof comprising a region where amino resides corresponding to at least a portion of a complementary determining regions (CDR) is replaced with

a peptide consisting of hBNP and hBNP mimetics, classified in class 514, subclass 2, for example.

XV. Claim 16 in part, drawn to a method of treating diabetes comprising administering to a subject an immunoglobulin molecule or fragment thereof comprising a region where amino resides corresponding to at least a portion of a complementary determining regions (CDR) is replaced with a peptide consisting of GLP-1 and GLP-1 mimetics, classified in class 514, subclass 2, for example.

XVI. Claim 16 in part, drawn to a method of treating diabetes comprising administering to a subject an immunoglobulin molecule or fragment thereof comprising a region where amino resides corresponding to at least a portion of a complementary determining regions (CDR) is replaced with a peptide consisting of GLP-2 and GLP-2 mimetics , classified in class 514, subclass 2, for example.

XVII. Claim 16 in part, drawn to a method of treating diabetes comprising administering to a subject an immunoglobulin molecule or fragment thereof comprising a region where amino resides corresponding to at least a portion of a complementary determining regions (CDR) is replaced with a peptide consisting of exendin and exendin mimetics, classified in class 514, subclass 2, for example.

XVIII. Claim 16 in part, drawn to a method of treating diabetes comprising administering to a subject an immunoglobulin molecule or fragment

thereof comprising a region where amino resides corresponding to at least a portion of a complementary determining regions (CDR) is replaced with a peptide consisting of glucagon and glucagon mimetics, classified in class 514, subclass 2, for example.

XIX. Claim 16 in part, drawn to a method of treating diabetes comprising administering to a subject an immunoglobulin molecule or fragment thereof comprising a region where amino resides corresponding to at least a portion of a complementary determining regions (CDR) is replaced with a peptide consisting of PACAP-38, classified in class 514, subclass 2, for example.

XX. Claim 17 in part, drawn to a method of treating obesity comprising administering to a subject an immunoglobulin molecule or fragment thereof comprising a region where amino resides corresponding to at least a portion of a complementary determining regions (CDR) is placed with a peptide consisting of hBNP and hBNP mimetics , classified in class 514, subclass 2, for example.

XXI. Claim 17 in part, drawn to a method of treating obesity comprising administering to a subject an immunoglobulin molecule or fragment thereof comprising a region where amino resides corresponding to at least a portion of a complementary determining regions (CDR) is placed with a peptide consisting of GLP-1 and GLP-1 mimetics, classified in class 514, subclass 2, for example.

XXII. Claim 17 in part, drawn to a method of treating obesity comprising administering to a subject an immunoglobulin molecule or fragment thereof comprising a region where amino resides corresponding to at least a portion of a complementary determining regions (CDR) is placed with a peptide consisting of GLP-2 and GLP-2 mimetics, classified in class 514, subclass 2, for example.

XXIII. Claim 17 in part, drawn to a method of treating obesity comprising administering to a subject an immunoglobulin molecule or fragment thereof comprising a region where amino resides corresponding to at least a portion of a complementary determining regions (CDR) is placed with a peptide consisting of exendin and exendin mimetics, classified in class 514, subclass 2, for example.

XXIV. Claim 17 in part, drawn to a method of treating obesity comprising administering to a subject an immunoglobulin molecule or fragment thereof comprising a region where amino resides corresponding to at least a portion of a complementary determining regions (CDR) is placed with a peptide consisting of glucagon and glucagon mimetics, classified in class 514, subclass 2, for example.

XXV. Claim 17 in part, drawn to a method of treating obesity comprising administering to a subject an immunoglobulin molecule or fragment thereof comprising a region where amino resides corresponding to at least a portion of a complementary determining regions (CDR) is placed with a

peptide consisting of PACAP-38, classified in class 514, subclass 2, for example.

XXVI. Claim 18, drawn to a method of preserving or improving beta-cell function comprising administering to a subject an immunoglobulin molecule or fragment thereof comprising a region where amino resides corresponding to at least a portion of a complementary determining regions (CDR) is replaced with a peptide consisting of GLP-1, classified in class 514, subclass 2, for example.

XXVII. Claim 19, drawn to a method of inducing endothelial-dependent relaxation of preconstricted pulmonary artery rings comprising administering to a subject an immunoglobulin molecule or fragment thereof comprising a region where amino resides corresponding to at least a portion of a complementary determining regions (CDR) is replaced with a peptide consisting of GLP-1, classified in class 514, subclass 2, for example.

XXVIII. Claims 20 and 21, drawn to a method comprising administering to a subject an Ig molecule or fragment thereof comprising a region where amino acid residues corresponding to at least a portion of a CDR replaced with a thiazolidinedione derivative, classified in class 514, subclass 2, for example.

XXIX. Claim 22, drawn to a method of regulating adiponectin expression comprising administering to a subject an Ig molecule or fragment thereof comprising a region where amino acid residues corresponding to at least a

portion of a CDR replaced with a thiazolidinedione derivative, classified in class 514, subclass 2, for example.

2. The inventions are distinct, each from the other because of the following reasons:

The of immunoglobulin molecule of Group I-VI and the polynucleotide of Group VII-XII are patentably distinct for the following reasons: The IgG molecule of Group I-VI consists of 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarily determining regions (CDRs). Polypeptides, such as the immunoglobulin molecule of Group I-VI which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. Therefore, the antibody and polynucleotide are patentably distinct. The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of Group I-VI and Group VII-XII would impose a serious search burden since a search of the immunoglobulin of Group I-VI would not be used to determine the patentability of any polynucleotide of Group VII-XII, and vice-versa. Thus, Groups I-VI and VII-XII represent separate and distinct inventions.

The inventions of Groups XIII-XXIX are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used,

response variables, and criteria for success. In the instant case, Group XIII recites a method of treating congestive heart failure comprising administering a subject an immunogenic molecule or fragment thereof and a method of producing an immunoglobulin molecule, wherein the immunoglobulin molecule or fragment thereof comprising a region where amino resides corresponding to at least a portion of a complementary determining regions (CDR) is replaced with a peptide consisting of hBNP and hBNP mimetics, Groups XIV-XIX recite a method of treating diabetes comprising administering to a subject an immunoglobulin molecule or fragment thereof comprising a region where amino resides corresponding to at least a portion of a complementary determining regions (CDR) is replaced with a peptide consisting of hBNP and hBNP mimetics, GLP-1 and GLP-1 mimetics, GLP-2 and GLP-2 mimetics, exendin and exendin mimetics, glucagon and glucagon mimetics and PACAP-38, respectively; Groups XX-XXV recite a method of treating obesity comprising administering to a subject an immunoglobulin molecule or fragment thereof comprising a region where amino resides corresponding to at least a portion of a complementary determining regions (CDR) is placed with a peptide consisting of hBNP and hBNP mimetics, GLP-1 and GLP-1 mimetics, GLP-2 and GLP-2 mimetics, exendin and exendin mimetics, glucagon and glucagon mimetics and PACAP-38, respectively; Group XXVI recites a method of preserving or improving beta-cell function comprising administering to a subject an immunoglobulin molecule or fragment thereof comprising a region where amino resides corresponding to at least a portion of a complementary determining regions (CDR) is replaced with a peptide consisting of GLP-1; Group XXVII

recites a method of inducing endothelial-dependent relaxation, of preconstricted pulmonary artery rings comprising administering to a subject an immunoglobulin molecule or fragment thereof comprising a region where amino resides corresponding to at least a portion of a complementary determining regions (CDR) is replaced with a peptide consisting of GLP-1; Group XXVIII recites a method comprising administering to a subject an Ig molecule or fragment thereof comprising a region where amino acid residues corresponding to at least a portion of a CDR replaced with a thiazolidinedione derivative; and Group XXIX recites a method of regulating adiponectin expression comprising administering to a subject an Ig molecule or fragment thereof comprising a region where amino acid residues corresponding to at least a portion of a CDR replaced with a thiazolidinedione derivative. Thus, each group differs in method objectives, method steps and parameters and in the reagents used. Further, each group is unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has different mode of operation. Each invention further performs this function using structurally and functionally divergent material. Moreover, the methodology and materials necessary for detection differ significantly for each of the materials. The examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability issues. Thus Inventions III-IX represent separate and distinct in having different method steps and different endpoints and are patentably distinct.

The inventions of Group I-VI and the method of Groups XIII-XXIX are related as product and process of use. The inventions can be shown to be distinct if either or both

of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the antibody product as claimed can be used in a materially different process such as affinity chromatography or immunoassays in addition to the materially different methods of Groups XIII-XXIX.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different searches in the patent literature and different classification, restriction for examination purposes as indicated is proper.

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process

claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parithosh K. Tungaturthi whose telephone number is 571-272-8789. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

Parithosh K. Tungaturthi, Ph.D.

April 29, 2005

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER